DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 8, 2014

DIAMOND DIAGNOSTICS, INC
KATHY CRUZ
QUALITY ASSURANCE MANAGER
333 FISKE ST
HOLLISTON MA 01746

Re: K133751
Trade/Device Name: Diamond Diagnostics ISE Serum Standards,
Diamond Diagnostics ISE Urine Standards
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: II
Product Code: JIT
Dated: June 23, 2014
Received: June 24, 2014

Dear Ms. Cruz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k133751

Device Name
Diamond Diagnostics ISE Serum Standards,
Diamond Diagnostics ISE Urine Standards

Indications for Use *(Describe)*

Diamond Diagnostics ISE Serum Standards are intended for in-vitro diagnostics to provide calibration points for the sodium, potassium, and chloride electrodes on ADVIA Chemistry systems in Human Serum mode.

Diamond Diagnostics ISE Urine Standards are intended for in-vitro diagnostics to provide calibration points for the sodium, potassium, and chloride electrodes on ADVIA Chemistry systems in Human Urine mode.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92

Applicant: Diamond Diagnostics Inc
333 Fiske Street
Holliston MA 01746

Contact Person: Kathy Cruz
Quality Assurance Manager
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www.diamonddiagnostics.com

Date Prepared: 08/05/14

Classification Name: Calibrator, secondary

Trade Name: Diamond Diagnostics ISE Serum Standards
Diamond Diagnostic ISE Urine Standards

Device Classification: 21 CFR 862.1150

Device Class: Class II

Classification Panel: Clinical Chemistry (75)

Product Code: JIT

Indications for Use: Diamond Diagnostics ISE Serum Standards are intended for in-vitro diagnostics to provide calibration points for the sodium, potassium and chloride electrodes on ADVIA Chemistry systems in Human Serum mode.

Diamond Diagnostics ISE Urine Standards are intended for in-vitro diagnostics to provide calibration points for the sodium, potassium and chloride electrodes on ADVIA Chemistry systems in Human Urine mode.

Description of Device: Diamond Diagnostics ISE Serum Standards and ISE Urine Standards are intended to serve as a direct replacement to Siemens (Bayer) Advia ISE Serum Standards and ISE Urine Standards.

Diamond Diagnostics ISE Serum Standards consists of an aqueous buffered solution of electrolytes, and preservative in Deionized water. It contains NO human or animal products. It is a liquid packaged in a 100mL high density polyethylene (HDPE) dropper bottle. It consists of one Serum Low Standard and one Serum High Standard sold as a set in a box.

The Serum Standards are comprised of the following concentrations of analytes.

	Na^+ mmol/L	K^+ mmol/L	Cl^- mmol/L
ISE Serum Standard Low	130 ± 2	3.5 ± 0.05	85 ± 2
ISE Serum Standard High	160 ± 2	6.0 ± 0.05	120 ± 2

Diamond ISE Urine Standards consists of an aqueous buffered solution of electrolytes, and preservative in Deionized water. It contains NO human or animal products. It is a liquid packaged in a 100mL HDPE dropper bottle. It consists of one Urine Low Standard and one Urine High Standard sold as a set in a box.

The Urine Standards are comprised of the following concentrations of analytes.

	Na^+ mmol/L	K^+ mmol/L	Cl^- mmol/L
ISE Urine Standard Low	50 ± 2	10 ± 0.2	50 ± 2
ISE Urine Standard High	200 ± 3	100 ± 2	180 ± 2

Predicate Device: Diamond Diagnostics ATAC 8000/Envoy 500 ISE Serum Calibrators

Predicate 510(k) number(s): k121027

Comparison with predicate:

Diamond Diagnostics ISE Serum Standards

Similarities and Differences		
Characteristics	**Candidate Device Diamond Diagnostics ISE Serum Standards (Low and High)**	**Predicate Device Diamond Diagnostics ATAC 8000/Envoy 500 ISE Serum Calibrators (k121027)**
Product Type	Calibrator	same
Intended Use	For in-vitro diagnostics use in the calibration of sodium, potassium, and chloride electrodes on ADVIA Chemistry systems in Serum mode.	For in-vitro diagnostics use in the calibration of sodium, potassium, chloride and CO2 electrodes on ATAC 8000/ Envoy 500 Chemistry systems.
Matrix	Aqueous buffered solution of salts & preservatives in Deionized water. Contains NO human or animal materials.	same
Levels	Low and High	same
Packaging	100mL HDPE Dropper Bottle, sold as a set of 1 each High and Low Standard	2 x 20mL Glass Vial
Storage	18-25 °C	same
Shelf Life	24 months	same
Open-Vial Stability	30 Day	Use immediately after opening

Diamond Diagnostics ISE Urine Standards

Similarities and Differences		
Characteristics	**Candidate Device Diamond Diagnostics ISE Urine Standards (Low and High)**	**Predicate Device Diamond Diagnostics ATAC 8000/Envoy 500 ISE Serum Calibrators (k121027)**
Product Type	Calibrator	same
Intended Use	For in-vitro diagnostics use in the calibration of sodium, potassium, and chloride electrodes on ADVIA Chemistry systems in Urine mode.	For in-vitro diagnostics use in the calibration of sodium, potassium, chloride and CO2 electrodes on ATAC 8000/ Envoy 500 Chemistry systems.
Matrix	Aqueous buffered solution of salts & preservatives in Deionized water. Contains NO human or animal materials.	same
Levels	Low and High	same
Packaging	100mL HDPE Dropper Bottle, sold as a set of 1 each High and Low Standard	2 x 20mL Glass Vial
Storage	18-25℃	same
Shelf Life	24 months	same
Open-Vial Stability	30 Day	Use immediately after opening

Stability:

Accelerated (high temperature) stress test was conducted to support the stability claim of 24 months when stored at 18℃ to 25℃. Heat stressed reagents showed that the ISE Serum Standards and ISE Urine Standards parameters remained within specification. Open-Vial Stability was conducted to support the claim of 30 days at 18-25°C. Open-vial reagents showed that the ISE Serum Standards and ISE Urine Standards parameters remained within specification. Real time stability studies are in progress and will commence at 6 month intervals for 2 years at 18℃ and 25℃. The solutions will be tested analytically for the electrolytes using reference methods. Flame Photometry will be used for the Na^+ and K^+. Silver/Silver Chloride Titration method is used for the Cl^-. Functional performance for calibration and control testing will likewise be performed.

Traceability:

All testing for analytes were conducted using Standards gravimetrically prepared from NIST salts. Testing was also conducted using reference methods.

Analyte	**Reference Standard Material Used for Determination of Analyte Value**	**Reference Method Used**
Na, K	NIST 919b, 918b	IL 943 (Flame Photometry)
Cl	NIST 919b	SAT-500 Salt Analyzer, (Titrimetric)

Value Assignment:

Target values were obtained by testing reagents analytically prior to bottling, adjusting if necessary to meet specifications, and prior to release to stock for distribution. Each ISE Serum Standard High/Low and ISE Urine Standard High/Low is tested for Na^+, K^+, and Cl^-, pH, conductivity, calibration and QC Control recovery.

- To assure reagents meet target values and are within the predetermined acceptance criteria reagents are tested analytically, adjusted if necessary to meet specifications, prior to bottling. Each is tested analytically during the bottling process and prior to release to stock for distribution.
- Six replicates of each sample are tested analytically for the electrolytes using reference methods. Flame Photometry is used for the Na^+ and K^+. Silver/Silver Chloride Titration method is used for the Cl^-. The IL 943 Flame Photometer is used for testing the Na^+ and K^+, and the SAT-500 salt analyzer is used for testing the Cl^-.
- Lot to lot variation is determined by analytically testing new lot vs. previous lot normalized to either an aqueous standard made with corresponding analyte NIST (National Institute of Standards and Technology) material or a known Calibrator.

Diamond ISE Serum Standard High/Low and ISE Urine Standard High/Low for ADVIA Chemistry Systems Target values:

ISE Serum Standard Low	Units	Target Value
Na^+	mmol/L	130 +/- 2
K^+	mmol/L	3.5 +/- 0.05
Cl^-	mmol/L	85 +/- 2

ISE Serum Standard High	Units	Target Value
Na^+	mmol/L	160 +/- 2
K^+	mmol/L	6 +/- 0.05
Cl^-	mmol/L	120 +/- 2

ISE Urine Standard Low	Units	Target Value
Na^+	mmol/L	50 +/- 2
K^+	mmol/L	10 +/- 0.2
Cl^-	mmol/L	50 +/- 2

ISE Urine Standard High	Units	Target Value
Na^+	mmol/L	200 +/- 3
K^+	mmol/L	100 +/- 2
Cl^-	mmol/L	180 +/- 2

Specific Standards and Concentrations used

Analyte	Standard	Concentration (mmol/L)
Na^+	NIST 919b	160, 140, 100, and 50
K^+	NIST 918b	100, 8, 5 and 0.5
Cl^-	NIST 919b	200, 125, 80, and 5

The target values were chosen to match the ADVIA ISE Serum Standards and ISE Urine Standards predicate.

Conclusion:

Based on the results submitted in this premarket notification Diamond Diagnostics ISE Serum Standards and ISE Urine Standards for Advia Chemistry systems are substantially equivalent to the Diamond Diagnostics ATAC 8000/Envoy 500 ISE Serum Standards in composition, and Intended use, for the calibration of Na+, K+, and Cl- Electrodes.